UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PharmacyChecker.com LLC,

Plaintiff,

vs.

National Association of Boards of Pharmacy et al.,

Defendants.

Civil Action No. 7:19-cv-07577-KMK

Plaintiff's Opposition to Defendants' Motion to Exclude the Expert Testimony of Benjamin England, Esq.

ORAL ARGUMENT REQUESTED

Judge Kenneth M. Karas
Magistrate Judge Paul E. Davison

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Benjamin England has decades of experience working within the FDA's regulatory scheme. He spent 13 years at the FDA, first as a compliance officer and later at the highest echelon of policymaking as regulatory counsel to the associate commissioner for regulatory affairs. He has consulted and served as an expert witness for countless companies and several states on issues relating to drug importation. Defendants concede that Mr. England is an expert on regulation and policy of U.S. drug importation and that his expertise and career knowledge is relevant and helpful to the issues of whether plaintiff's business is "almost completely" illegal or facilitates illegality. Rather, defendants assert Mr. England should be excluded because: (i) his testimony "goes [] to" an "ultimate issue" and he draws legal conclusions about the regulatory scheme at issue, and (ii) defendants believe he is wrong about the way the regulatory scheme works. Mem. of Law in Supp. of Defs.' Mot. to Exclude the Expert Test. of Benjamin England, Esq. ("Mem.") at 5–9. Neither of these assertions provides a basis to exclude Mr. England's testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579 (1993), and its progeny. Defendants also incorrectly claim Mr. England did not do enough homework, that he impermissibly opines about plaintiff's state of mind, and that he speculates about FDA officials' individual discretion.

Defendants' motion should be denied. First, the federal rules do not preclude testimony on an ultimate issue, and defendants are incorrect that legal testimony is *per se* inadmissible. In fact, this Court has held that the "crucial distinction is that an expert may not draw ***the final inference*** between relevant evidence and the

ultimate conclusion the jury will be asked to make." *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig. v. Exxon Mobil Corp.*, No. 00 CIV 1898 (SAS); 04 Civ. 3417 (SAS), 2009 U.S. Dist. LEXIS 63563, at *57–59 (S.D.N.Y. July 21, 2009) (emphasis added). Second, the correctness of an expert's opinion is not a basis for exclusion. In any event, defendants are simply wrong about that: importation is not always unlawful and their reliance on dicta in an out-of-circuit decision—*In re Canadian Import Antitrust Litigation*—is misplaced. 470 F.3d 785 (8th Cir. 2006). Finally, defendants' arguments about Mr. England not doing enough homework, testifying about plaintiff's state of mind, and basing his opinion on individual FDA officer meritless distortions of the record.

STATEMENT OF FACTS

This case is about defendants' illegal conspiracy to eliminate plaintiff as a source of drug pricing information and online pharmacy. Defendants argue plaintiff has no standing to challenge their *per se* antitrust violation because plaintiff's enterprise is "almost completely geared toward facilitating illegality." Mem. at 6. Because defendants put plaintiff's conduct at issue, plaintiff engaged Mr. Ben England, an expert on the FDA and the regulatory scheme governing drug importation.

Defendants do not dispute that Mr. England is qualified. He was a consumer safety and compliance officer in the FDA for three years. In that role, he determined compliance of food, drug and other products with the governing regulations, and initiated enforcement actions against misbranded and unapproved products to allow or prevent their distribution in the United States. Expert Rep. of Benjamin L.

England, Esq. ("Rep.") at 1–2 (Declaration of James Lerner ("Lerner Decl."), Ex. 1). Mr. England also supported prosecutions and investigations of companies allegedly involved in distribution of misbranded, adulterated and unapproved drugs and drug products. *Id*. He routinely applied the FDA's Personal Importation Policy ("PIP"), which allows the importation of unapproved drugs that are clearly for personal use. *Id*.

For the next six years, Mr. England was a special agent at the FDA Office of Criminal Investigations where he investigated criminal violations of the Food, Drug and Cosmetic Act ("FDCA"), including misbranding and adulteration violations. *Id.* at 2. And for another four years, he was regulatory counsel to the associate commissioner for regulatory affairs where he provided legal advice to the FDA regarding application of the FDCA and FDA regulations; in that role, he also served as lead FDA liaison to the U.S. Department of Agriculture and to Customs and Border Protection for nationwide enforcement of the FDCA and FDA regulations, including the PIP. Mr. England also trained many officers and investigators regarding the application of the relevant regulatory regime. *Id.*

Mr. England has provided counsel to top FDA officials testifying before Congress regarding personal importation, and throughout his career, taught FDA, customs and state regulatory officials and industry representatives the proper interpretation, enforcement and application of the FDCA, FDA regulations, and guidance. *Id.* Mr. England "performed hundreds of reviews of drugs and medical devices imported by individual consumers, clinics, physicians and pharmacies," and

"hundreds of label reviews for clients' FDA-regulated products, including over-the-counter and prescription drugs." *Id.* at 1, 3.

Plaintiff proffers Mr. England's testimony that, based on his experience and knowledge of the applicable law, personal prescription drug importation is not illegal in many circumstances. More specifically, Mr. England's conclusions are:

1. Drugs that comply with the FDA's labeling and approval requirements may be imported legally.

2. Drugs that comply with the FDA's approval requirements except for labeling and packaging may be imported legally.

3. As mandated by Congress, the FDA has guidance called PIP that explains to consumers when importation of prescription drugs is permissible under the relevant laws.

4. With the above as context, Mr. England opines that plaintiff's requirements for pharmacy participation in its accreditation program, as stated on its website, are consistent with PIP and designed toward compliance with lawful importation.

Id. at 5.

As Mr. England's report explains, these conclusions are grounded in his career knowledge and experience, as well as the following materials he relied upon specifically for this case:

- Federal Food Drug and Cosmetic Act, as amended (publicly available)
- Federal Register Notices published in conjunction with FDA's issuance of various regulations (publicly available)
- FDA regulations (publicly available)
- FDA guidance documents, statements and procedures related to importation (publicly available)
- Amended Complaint
- Pharmacychecker.com website
- Pharmacychecker.com 30(b)(6) deposition transcript and the 40-plus exhibits thereto.

Lerner Decl., Ex. 2.

Mr. England is not being proffered to testify whether plaintiff's enterprise is "completely or almost completely geared toward facilitating illegality," and he expresses no opinion whether plaintiff's "primary purpose" is to facilitate unlawful prescription importation into the United States. Nor is Mr. England being proffered to opine how individual FDA compliance officers exercise discretion.

Defendants elected to submit no expert testimony to support their claim that the importation of prescription drugs to the United States is across-the-board illegal or to otherwise rebut Mr. England's testimony.

LEGAL STANDARD

Admissibility under the Federal Rules of Evidence is liberal so that only "serious flaws" in an expert's testimony preclude admission within the broad discretion of the trial court. *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 173 (S.D.N.Y. 2009); *Amorgianos v. Amtrak*, 303 F.3d 256, 267 (2d Cir. 2002) (cited by defendants; stating that the *Daubert* standard is liberal and flexible, allowing for all reliable expert testimony to be admitted even if it's debatable). Otherwise, an expert's testimony, so long as helpful and sufficiently reliable, should be "tested by the adversary process," rather than "excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." *Fosamax*, 645 F. Supp. 2d at 173 (citations omitted).

Expert testimony based on career knowledge is admissible, the same as testimony based on a scientific method, and courts routinely admit testimony from former government agents, including from the FDA, as uniquely helpful to the fact-

finder's understanding of complex regulatory schemes. *Id.* at 191 ("A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical industry. [The expert's] assessment of the reasonableness of Merck's conduct in light of her experience and her understanding of FDA regulations will be helpful to the jury."); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

The "correctness" of an expert's testimony is a factual inquiry that should be left to the jury after considering competing expert testimony and cross-examination, while the trial court's function under *Daubert* is to exclude junk science masquerading as expertise. *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF; MDL No. 2100, 2011 WL 6302287, at *3 (S.D. Ill. Dec. 16, 2011); *Kumho Tire*, 526 U.S. at 159.

ARGUMENT

I. MR. ENGLAND'S TESTIMONY IS ADMISSIBLE AND DOES NOT CONSTITUTE AN ULTIMATE LEGAL CONCLUSION

Mr. England's first three opinions are that prescription drug importation is not always illegal, i.e., when the product is (i) FDA-approved and not misbranded; (ii) FDA-approved and misbranded but satisfy other conditions; or (iii) fall under FDA's PIP. Defendants argue that these opinions should be stricken because they "go [directly] to" an "ultimate issue," and are "squarely" directed at "legality." Mem. at 5–7. Defendants' version of the applicable law is overly simplistic and erroneous.

The Federal Rules of Evidence do not preclude opinions that go to ultimate

issues. Fed. R. Evid. 704(a) (an "opinion is ***not*** objectionable just because it embraces an ultimate issue") (emphasis added). And defendants are wrong that legal testimony is *per se* inadmissible. Mem. at 5–6. As this Court has confirmed, rather than exclude expert opinion merely because it involves legal conclusions, the rules go instead to how legal opinions are framed:

> At its essence, Rule 704 restricts how an expert may frame her opinions. . . . [An expert] may opine that a defendant acted outside of established guidelines, but she may not opine that the defendant acted *negligently* or *recklessly*. The crucial distinction is that an expert may not draw ***the final inference*** between relevant evidence and the ultimate conclusion the jury will be asked to make. Such impermissible testimony is most easily banished from the courtroom by cautioning experts not to use words with 'a specialized legal meaning that is more precise than the lay understanding of the term.' Within the courts of the Second Circuit, an expert may lead a jury to the precipice of a verdict, but she may not instruct them to leap.

Methyl, 2009 U.S. Dist. LEXIS 63563, at *57–59. (emphasis added).[1]

The comments to Rule 704 illuminate this sometimes-fine line between

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1. Many other decisions are in accord that "legal" testimony is not *per se* inadmissible. *See, e.g., Town of Halfmoon v. GE*, No. 1:09-CV-228, 2016 U.S. Dist. LEXIS 26888, at *45–48 (N.D.N.Y. Mar. 3, 2016) ("[T]he mere fact that an expert's opinion is based on criteria delineated by the applicable law does not transmogrify it into a legal conclusion."); *United States v. Rankin*, No. 3:18-cr-272 (JAM), 2021 U.S. Dist. LEXIS 227387, at *13 (D. Ct. Nov. 27, 2021) ("If, for example, the prosecution alleges that a defendant has engaged in overt acts to perpetrate or conceal a charged crime, the jury's evaluation of whether the defendant engaged in the acts for a nefarious purpose may turn in whole or in part on whether the overt acts are themselves allowed under background or subsidiary principles of criminal or civil law. So the fact that the defendants propose that [a professor] testify about . . . the business judgment rule [argued to communicate a legal standard to the jury] is not itself a reason to preclude the testimony."); *Hatala v. Port Auth. of NY & NJ*, No. 15 Civ. 9218 (AA) (JCF), 2017 U.S. Dist. LEXIS 230651, at *12 (S.D.N.Y. Oct. 30, 2017) (expert may offer helpful background on typical procedures in airport management, including whether defendants departed from them, as opposed to testifying that defendants breached the applicable duty of care or were "negligent").

admissible expert opinion and ultimate legal conclusions: "an expert may not render any ultimate opinion concerning, for example, whether a specific party had 'capacity to make a will,' but may offer an opinion concerning whether that party had 'sufficient mental capacity to know the nature and extent of his property and the natural objects of his bounty and to formulate a rational scheme of distribution." *Krys v. Aaron*, 112 F. Supp. 3d 181, 192–93 (D.N.J. 2015) (citing Fed. R. Evid. 704). In other words, "an expert may not make a conclusory statement on a party's capacity but may provide testimony that touches the underlying issues relevant to a determination of capacity." *Krys*, 112 F. Supp. 3d at 193. In *Krys*, for example, a law professor was allowed to opine whether conduct was generally inconsistent with federal securities laws, but he could not instruct the jury that a "party did indeed violate an applicable duty through certain actions." *Id.* (redacting only the impermissible opinion that a party had ***in fact*** breached the applicable legal duties by engaging in particular conduct).

The admission of expert testimony is particularly apt in cases involving a specialized industry or complex regulatory scheme where courts routinely allow experts to interpret regulatory requirements and procedures because "a lay jury cannot be expected to understand the complex regulatory framework that informs" the legality of the actor's conduct. *Fosamax*, 645 F. Supp. 2d at 191. *Utica Mut. Ins. Co. v. Munich Reinsurance Am., Inc.*, Nos. 6:12-cv-00196 (BKS/ATB); 6:13-cv-00743 (BKS/ATB), 2018 WL 3135847, at *6–7 (N.D.N.Y. June 27, 2018) (citations omitted) ("Experts may testify on mixed questions of fact and law," expert testimony is "not objectionable merely 'because it embraces an ultimate issue;' . . . [o]pinion testimony

that arguably states a legal conclusion may be helpful and admissible if the case involves a specialized industry."); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, MDL NO. 2445, 13-MD-2445; CIV. A. NO. 16-5073, 2020 WL 6887885, at *45 (E.D. Pa. Nov. 24, 2020) (citations omitted) ("[E]xpert testimony that implicates or touches on legal issues is not *per se* inadmissible. . . . Courts recognize that where expert testimony concerns the interpretation or explanation of complex areas of law difficult for a layperson to understand, expert testimony may be proper.").

In *Fosamax*, for example, a state law tort case, three FDA experts were permitted to "testify on regulatory issues, including [defendant's] adherence to FDA regulations and the appropriateness of [defendant's] conduct during the FDA approval . . . phase" because such testimony would be helpful to the jury's understanding of the FDA regulatory scheme. *Fosamax*, 645 F. Supp. 2d at 201, 209 (competing expert testimony and cross-examination will allow the jury to carefully weigh such testimony).

In *Yasmin*, a former FDA commissioner was allowed to testify that the defendant had "violated its duties under FDA regulations and state law by selectively presenting data . . . which did not adequately inform [the] FDA," and that the defendant had "engaged in extensive off-label promotion" "in violation of FDA regulations." *Yasmin*, 2011 WL 6302287, at *10 (noting that at trial, the jury can be instructed that the court, not any witness, will instruct the jury on the law that applies in the case). A second regulatory expert was permitted to testify "about the

meaning of specific FDA regulations or whether [the defendant] violated those regulations" and "statements of [the expert's] understanding, as an expert working in the field, of what the applicable regulations require and her expert analysis of the facts." *Id*. at *19.

Many other decisions accord:

- While "this circuit is in accord with other circuits in requiring exclusion of expert testimony that expresses a legal conclusion, expert testimony is viewed as helpful in cases, like this one, involving complex statutes or issues outside of the general knowledge of the jury." The court, therefore, allowed a professor to explain the procedures used to enforce the "complex law" governing drug approval, but disallowed an opinion that defendant's specific conduct actually violated the relevant laws. *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 184 (S.D.N.Y. 2018) (citations omitted).
- Allowing testimony by an expert "intimately familiar with FDA regulations" regarding the "proper interpretation of generally applicable biological licensing FDA regulations, as well as drug product salvaging regulations." *Am. Home Assur. Co. v. Merck & Co.*, 462 F Supp. 2d 435, 451–52 (S.D.N.Y. 2006) (also allowing a second regulatory expert to testify regarding her "reasonable interpretation of regulations").
- Allowing testimony of a former FDA employee based on her specialized knowledge of the relevant regulations, how these regulations are interpreted and implemented by the FDA and the collaborative process between

manufacturers and the FDA in ensuring compliance with these regulations. *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 465 (E.D.N.Y. 2011).

- Allowing an expert's assessment of the reasonableness of the defendant's conduct "in light of her experience and her understanding of FDA regulations," which are helpful to the jury. "An expert may offer testimony embracing an ultimate issue of fact . . . . Cross-examination and competing expert testimony by [defendant's] regulatory experts will ensure the jury carefully weights her testimony." *Suboxone*, 2020 WL 6887885, at *44–45 (citations omitted) (excluding only the conclusions that matched questions to be submitted to the jury, i.e., that defendants did make "false and misleading" statements under the FDCA).
- Permitting a former FDA Commissioner to testify regarding the FDA's regulatory scheme in general, FDA practices and procedures, the defendant's compliance with FDA regulations, and a party's knowledge "if a jury would not otherwise understand the importance of certain facts without the benefit of his expertise—for example what is or is not common knowledge in the pharmaceutical company community based on his experience at the FDA," among other subjects. *Drake v. Allergan, Inc.*, No. 2:13-cv-234, 2014 WL 5392995, at *6 (D. Vt. Oct. 23, 2014) (noting that whether specific testimony at trial crosses the line can be adequately addressed at that time).[2]

2. To the extent the *Fosamax* cases are distinguishable because the alleged claims in those cases were based on state law—rather than the FDA regulations

Based on the above, Mr. England's first three opinions are admissible. According to defendants, the ultimate "question" here is "whether Plaintiff's enterprise is completely or almost completely geared towards facilitating illegality" by "providing U.S. consumers with links to international online pharmacy websites where they can and do purchase prescription drugs for importation to the United States." Mem. at 4–5. Mr. England's first three opinions are generic—importation of prescription drugs is not illegal so long as certain conditions are met. These opinions helpfully inform the jury about the relevant regulatory scheme without discussing the operative legal standard or applying law to facts. Mr. England does not say anything about plaintiff in these three opinions, let alone dictate the final result whether plaintiff is "geared toward" facilitating illegality or to what degree.[3] Any

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themselves—that distinction makes no sense because the claim involved here is based on the Sherman Act. But even if breaches of the FDA's regulatory scheme ***did*** form the basis for plaintiff's cause of action, decisions permitting expert testimony going to the applicable regulations or contract language in those circumstances bely defendants' argument. *See, e.g.*, *Krys*, 112 F. Supp. 3d at 192–93 (allowing an expert to conclude that defendant's conduct was not consistent with federal securities laws while those same laws formed the cause of action); *Alto v. Sun Pharm. Indus.,* No. 1:19-cv-09758-GHW, 2021 WL 4803582, at *11 (S.D.N.Y. Oct. 13, 2021) (allowing two experts to testify as to "commercial reasonableness" based on their industry experience even though plaintiffs alleged breach of a "commercial reasonableness" contractual provision as a cause of action).

3. In this respect and others, defendants' cited authorities are inapposite. *In re Air Disaster at Lockerbie Scot.*, 37 F.3d 804, 827 (2d Cir. 1994) (expert testimony should have been excluded because "Pan Am did indeed violate the ACSSP" crossed the "fine line between a permissible conclusion as to an ultimate issue of fact and an impermissible legal conclusion," but hastening to add that the error was harmless because, among other reasons, the court instructed the jury that it was the ultimate judge of liability); *Giles v. Rhodes*, No. 94-cv-6385 (CSH), 2000 U.S. Dist. LEXIS 13980, at *51 (S.D.N.Y. Sept. 26, 2000) (excluding, in an excessive force case, the expert's recitation of the governing legal standard and the conclusion that the

potential concerns that Mr. England's testimony comes close to the line (plaintiff does not think it does) are addressable at trial through cross-examination, competing expert testimony, and limiting instructions. (Defendants could have proferred competing expert testimony but chose not to.)

II. WHETHER MR. ENGLAND'S OPINIONS ARE CORRECT IS NOT A *DAUBERT* QUESTION

Defendants argue that Mr. England's report is substantively incorrect based, in large part, on a 2006 out-of-circuit decision on a motion to dismiss. But substantive correctness is not a proper *Daubert* attack, particularly in the absence of controlling and well-settled law that negates the testimony at issue. *Showers v. Pfizer, Inc.*, 819 F.3d 642, 662 (2d Cir. 2016) (the *Daubert* analysis should be done without regard to the conclusions the expert has reached or the court's belief as to the correctness of those conclusions). *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) ("[t]he soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, summary judgment); *In re LIBOR-Based Fin. Instruments Antitrust Litig.,* 299 F. Supp. 3d 430, 467 (S.D.N.Y. 2018) ("[T]he reliability inquiry 'must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or

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defendants' actions "withstand the scrutiny" when "you apply" the legal standard); *Feinberg v. Katz*, No. 01 Civ. 2739 (CSH), 2007 U.S. Dist. LEXIS 94967, at *24–25 (S.D.N.Y. Dec., 21 2007) (excluding testimony that an omission from a financial statement was "material" where "material" was the governing legal standard and that exact question mixed of law and fact was to be resolved by the jury); *George v. Kraft Foods Glob., Inc.*, 800 F. Supp. 2d 928, 932 (N.D. Ill. 2011) (excluding an expert's "redefinition" of the applicable standard of care for liability under ERISA).

our belief as to the correctness of those conclusions.' ").

Defendants' own authorities bear this out. *Lamar Advert. Co. v. Zurich Am. Ins. Co.*, 533 F. Supp. 3d 332, 344 (M.D. La. 2021) (disallowing expert testimony contrary to rulings previously made on summary judgment in the same case and inconsistent with principles "well-settled" under controlling state law authorities; allowing expert testimony about the relevant legal relationship and duties owed, as well the meaning of an insurance policy's specific terms); *Mars, Inc. v. TruRX LLC*, No. 6:13-cv-526-RWS-KNM, 2016 U.S. Dist. LEXIS 121889, at *7–8 (E.D. Tex. Apr. 18, 2016) (excluding, in a patent dispute, expert legal opinions that directly contradicted controlling Federal Circuit precedent); *George*, 800 F. Supp. 2d at 934 (excluding expert testimony stating a standard of care for liability inconsistent with the standard provided by controlling state statute); *cf Loeffel Steel Prods., Inc. v. Delta Brands, Inc.*, 387 F. Supp. 2d 794, 806 (N.D. Ill. 2005) (excluding a made-up damages theory that, unlike here, had no support anywhere).

Even if the Court does consider the substantive correctness of Mr. England's conclusions on this motion, the independent legal support for the proposition that prescription importation is not totally illegal is more fully set out in plaintiff's opposition to defendants' motion for summary judgment. Pl.'s Opp'n to Defendants' Joint Mot. for Summ. J. on Sherman Act § 1 Claim at 21-26.

For *Daubert* purposes, it suffices to say that Mr. England's opinion—that personal importation of prescription drugs is legal in various circumstances—is verifiably correct. For one thing, the FDA's own website explains:

> In ***most*** circumstances, it is illegal for individuals to import drugs or devices into the U.S. for personal use because these products purchased from other countries ***often have not been approved*** by the FDA for use and sale in the U.S. For example, a drug approved for use in another country but not approved by the FDA would be ***considered an unapproved drug in the U.S. and, therefore, illegal to import***.

www.fda.gov/industry/import-basics/personal-importation (emphasis added). This squares with Mr. England's considerable experience that prescription drugs can be imported, among other ways, if they are (i) FDA-approved and not misbranded or (ii) FDA-approved and misbranded, but satisfy other conditions. Lerner Decl., Ex. 1 at 5.

Against this, defendants hang their hat on a passing comment from an out-of-circuit decision, i.e., that the FDA's system is "closed." Mem. at 10 (citing *Canadian Imp.*, 470 F.3d at 790). But Mr. England thoroughly testified in response to specific questions about *Canadian Import* that, in practice, the reality is more complicated and "closed" is more nuanced—no drugs made overseas are subject to an entirely closed system (and that includes drugs dispensed in the United States, most of which are manufactured outside the United States):

> A: Yeah, the distinction I'm making is the domestic versus the foreign closed system concept, right? So even in the most heavily regulated environment, that is as closed as you get.
>
> Q: You are referring to the domestic market?
>
> A: Correct. U.S. made drugs in the United States market being distributed in the United States and then dispensed in the United States to U.S. consumers. That's the most closed we get . . . Once you introduce foreign components to that supply chain, you have lost the closed nature of it, and it doesn't matter whether it's coming from a pharmacy or its coming from the FDA-approved manufacturer. Once it gets into that supply chain, yes, the FDA has an expectation of whether it's going to come because they are familiar with that supply chain, but that is not in the approval. The distribution system is not

included in the [New Drug Approval]. So that's not closed the way the U.S. system is closed domestically.

Q: So closed is a misnomer as applied in your opinion, closed system is a misnomer as applies to the nondomestic drug supply?

A: That's correct. Whether it's the finished drug subject to the [New Drug Approval,] the 17 excipients, the APIs, that's true about every component, the labeling, the packaging, all of that is just flowing around the world and the government is not regulating it.

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Q: "Congress created a closed system designed to guarantee safe and effective drugs for consumers in the United States." Do you agree with that statement?

A: Largely yes, but the fact of the matter is back to what I said before, FDA doesn't regulate the distribution of the product in the foreign market . . . the distribution, the movement of the product in the foreign market. There just is no regulatory construct for it . . . I think it's fair—it's fair to use that characterization if we are talking about drugs made in the United States, but I don't think it's fair to say about drugs made overseas, because there are components of the system that are not regulated by the FDA.

Q: So drugs made overseas are not subject to the closed system. Is that an accurate statement?

A: That's true. If I could say, they are not subject to the same closed system as there is in the United States, drugs made in the United States . . . It's largely because of the distribution aspect of it.

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Q: Once an FDA-approved drug exits the FDA's closed system, the drug becomes unapproved.

A: I disagree.

Q: On what basis?

A: FDA doesn't have a closed system. There is no such thing as an FDA closed system.

Q: The FDA itself, though, has referred to a closed system in referring to its own regulatory regime, has it not?

> A: Yes, but they are not speaking in terms—they are not speaking legally. They are talking about structurally.
>
> Q: Okay.
>
> A: They are talking about the fact that they understand the parties in the supply chain, but that doesn't—that doesn't make the drug unapproved if it is outside that—that supply chain.

Mar. 16, 2022 videotaped Dep. of Benjamin L. England ("England Tr.") 226:20–227:19; 247:1–248:15; 259:6–260:20 (Lerner Decl., Ex. 3).

In contrast to Mr. England's careful examination of each of the exceptions, exemptions, and waivers allowing importation, as detailed in his report and grounded in his career, the Eighth Circuit seems to have borrowed the term "closed," from a Vermont decision, with no discovery or investigation regarding what the FDA meant. *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 472 (D. Vt. 2005). The Eighth Circuit's comment is also *dicta* because it is unnecessary to the far narrower holding, i.e., that "the Canadian prescription drugs at issue are not labeled in conformity with federal law," and thus, illegal to import under the particular regulations that the plaintiff-class invoked. *Canadian Imp.*, 470 F.3d at 789–91. And it is unpersuasive here as the decision lacks actual analysis of the exceptions, exemptions and waivers that Mr. England dissects in his report. What analysis it does attempt is not correct. Pl.'s Opp'n to Defendants' Joint Mot. for Summ. J. on Sherman Act § 1 Claim at 22–26.

Next, defendants argue that PIP does not support Mr. England's testimony that importation can be legal because PIP is a policy, and not an actual law. Mem. at 10. But defendants ignore Mr. England's deposition testimony, uncontroverted in the record, that 21 U.S. Code § 384(j) is the codified law that requires the FDA to follow

its own guidance laying out when the agency will consistently exercise its discretion to allow importation of drugs that otherwise would not be permitted:

> A: [T]he FDA officers now are operating under [PIP] guidance and there is discretion going on, but it is not the guidance. The guidance isn't the discretion. It's their activity that is discretionary.
>
> Q: And the thing that you are saying that they are operating under where Congress said –provides them guidance, is that 384(j).
>
> A: That's the—that's the statutory mandate, right?

Lerner Decl., Ex. 3. at 113:3–13.

Defendants' next argument—that 384(j) is meaningless because it has never been specifically certified by the HHS secretary—ignores Mr. England's undisputed testimony that 384(j) is self-executing and effective so far as FDA practice is concerned:

> A: I would say that 384(j) is effective because the FDA is only required to publish and update as necessary and this is (j)(2)(b) guidance which actually describes circumstances in which the secretary will consistently grant waivers on a case-by-case basis, and they are doing that on a real time basis in terms of the importation. . .
>
> Q: So what on the face of 384(j) or otherwise indicates that any of these provisions are self-executing?
>
> A: I find repeatedly throughout this provision, this section, the requirement for the FDA to establish regulation, to use—to implement by regulation. Except in this case, we have FDA being instructed to implement by guidance, so I'm going to—I take that to mean that the FDA is implementing it by guidance is agreeing that they do not need a regulation to do so, so that can implement it based upon the statutory language.

Id. at 179:9–180:11. If defendants wish to argue otherwise, i.e., that 384(j) had no effect, they can cross-examine Mr. England about how FDA practice treats it at trial.

Finally, defendants' claim that Mr. England testified at his deposition that the

regulations allow any pharmacist to put a drug in the mail and send it to the United States is a blatant misrepresentation of the record. Mem. at 12. To the contrary, the testimony that defendants cite, in its full context, is about just one requirement for a particular labelling exemption. Mr. England testified there are ***additional*** requirements, for example, that the pharmacy also comply with the various requirements under 201.100(b). Lerner Decl., Ex. 3 at 297:15–19; 299:4–300:17. If defendants believe that Mr. England is wrong, their recourse is cross-examination—not full exclusion based on a fractured misrepresentation of Mr. England's testimony.

In any event, given the complexity of the "closed" concept, among other FDA-related constructs, defendants' motion only highlights why Mr. England's testimony will be helpful to the jury to grasp the relevant nuances that defendants' motion ignores.

III. MR. ENGLAND'S TESTIMONY ABOUT PLAINTIFF'S WRITTEN PROGRAM IS WELL-GROUNDED AND NOT SPECULATIVE

Mr. England's fourth opinion is that plaintiff, which is not involved in any drug transactions, has an accreditation program with requirements that are consistent with legal importation rules. Lerner Decl., Ex. 1 at 5. (The PharmacyChecker.com "requirements for pharmacy participation in the accreditation program are clearly consistent with FDA's Personal Importation Policy and designed to ensure participating pharmacies conform to the FDA policy as mandated by Congress.").

First, defendants argue that the lack of involvement in actual transactions is not relevant to whether plaintiff's business "completely or almost completely" facilitates illegality (rather than being illegal in and of itself). As defendants are conceding that

plaintiff is not acting illegally and not involved in prescription drug transactions (import or otherwise), the argument to splice Mr. England's testimony in this way makes no practical difference because the record is uncontroverted. Mem. at 16 (conceding that "facilitation" is the only relevant issue).

Second, defendants' argument that Mr. England's testimony is about "intent or motive" is wrong. *Id*. at 17. This situation is just like the one in *Halfmoon* where the defense intended to call a former EPA officer, then at a consulting firm, to address whether a county's "response costs" were recoverable as damages because they were "necessary" under the National Contingency Plan ("NCP"). The expert was to testify that the costs were not "necessary" and were inconsistent with the NCP because the county failed to (i) evaluate the appropriate risks; (ii) consider alternative methods to address them; and (iii) utilize public participation. *Halfmoon*, 2016 U.S. Dist. LEXIS 26888, at *43–47. Presumably, as to what the county considered or not, the county argued that the expert's opinions were "based on his conclusions about the 'motivations and intent' of [institutional] decision-makers." *Id.* at *46. The Court disagreed: as defendant "correctly responds, [the] expert report does not 'rest on any effort to read [defendant's] institutional mind.' Instead, [the] opinions are based on a review of the paper trail created by [defendant] . . . and an examination of whether or not any documentary evidence produced in discovery substantiates [defendant's] claim . . . ." *Id.*

Mr. England is not being proffered to testify as to the institutional intent or motive of plaintiff when it created its accreditation program. Mr. England's

statement—that plaintiff's written accreditation program, as shown on its website, was "designed" in compliance with the applicable laws and policies—is Mr. England's interpretation of the written language of the program and is admissible. *See also Yasmin*, 2011 WL 6302287, at *19 (allowing testimony argued to go to "state of mind" where expert disclaimed any intent to testify as to motive with the court noting that any overstep is addressable at trial); *id.* (holding that exclusion motion is moot where it was represented that the expert was "not being proffered to provide [] unsupported opinions [about institutional intent], but rather [to] explain the FDA's regulatory system to the jury and explain the ways in which [the defendant] failed to comply;" noting that defendants could make an appropriate objection at trial if necessary).

The *Rezulin* decision, cited by defendants, is easily distinguished. There, the court excluded testimony speculating as to the "real motiv[ations]" of the parties, what the FDA "might have done" with different information, and what a party was thinking "for sure" based on a writing. *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546–47 (S.D.N.Y. 2004). This Court explained that such testimony is impermissible because it inferred for the jury what the parties' internal motivations were, e.g., increased profits. *Id.* Here, Mr. England infers nothing about plaintiff's motivations—only what the design of the written accreditation program is as stated on its face.

Next, defendants argue that Mr. England should have done something more, besides review PharmacyChecker.com, in reaching his fourth opinion. This again misrepresents the record. All the materials that Mr. England reviewed in this case

are set forth in his report and include 368 pages of deposition testimony and 305 pages of documents produced in discovery. Lerner Decl., Ex. 2 (England Report Ex. 2). The argument that Mr. England did not read enough deposition transcripts goes only to weight. *Hopkins v. AMTRAK*, No. 08-CV-2965 (NGG) (RML), 2015 WL 13741721, at *15 (E.D.N.Y. Aug. 20, 2015), (argument that an expert should have conducted more research goes only to credibility and weight); *Wright v. Stern*, 450 F. Supp. 2d 335, 360 (S.D.N.Y. 2006) (argument that expert should have reviewed more evidence goes to weight only).

Moreover, defendants' argument ignores the narrow scope of Mr. England's fourth opinion—that plaintiff's written accreditation program is consistent with the laws and regulations permitting importation. Mr. England is not being proffered to opine as to plaintiff's performance in implementing and enforcing its policies. And he is not being proffered to opine as to whether any one pharmacy complies with applicable regulations. Given this, Mr. England's review of the website and a 30(b)(6) deposition and its 41 exhibits that comprehensively discusses plaintiff's verification program provides all the facts needed for opinion four.

Finally, defendants claim that Mr. England's testimony is inconsistent with the testimony of an officer of plaintiff. Mem. at 18. But that argument goes only to weight, and defendants are free to cross-examine Mr. England about the purported discrepancy at trial. *United States v. Jones*, 965 F.3d 149, 162 (2d Cir. 2020) (argument that expert assumption was incorrect goes only to weight and not admissibility); *United States v. Mustafa*, 753 F. App'x 22, 36 (2d Cir. 2018) ("Factors

which make evidence less than conclusive affect only weight, not admissibility."); *SourceOne Dental, Inc. v. Patterson Cos.*, No. 15-cv-5440 (BMC), 2018 WL 2172667, at *8 (E.D.N.Y. May 10, 2018) (argument that expert "overlooked facts and information that contradict or do not support his opinions" is "exactly the type that can be effectively addressed through cross-examination").

IV. MR. ENGLAND DOES NOT OPINE ABOUT INDIVIDUAL FDA OFFICER DISCRETION

Defendants' bid to exclude Mr. England's purported testimony about how individual officers exercise their discretion is moot. Mem. at 14–15. Mr. England is not being proffered to opine about individual-officer decision-making, and officer discretion is not a basis for his opinions. That subject is defendants' tangent that they contrived at Mr. England's deposition where he testified, in response to their questions that, in enforcing PIP or any other policy, compliance officers have discretion—just as police officers have discretion—but that they are generally expected to follow policy and their training. Lerner Decl., Ex. 3 at 40–44, 55–56, 276.

CONCLUSION

For all of these reasons, defendants' motion to exclude Mr. England's testimony should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Lisa Mittwol, hereby certify that on this 20th day of July 2022, I caused a copy of Plaintiff's Opposition to Defendants' Motion to Exclude the Expert Testimony of Benjamin England, Esq. be served upon counsel of record via the Court's electronic filing system.

LISA MITTWOL